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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,753	07/25/2007	Henrik Arnberg	15665-010US1	3748
26191 7590 08/19/2010 FISH & RICHARDSON P.C. PO BOX 1022			EXAMINER	
			CHANDRA, GYAN	
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)		
10/599,753	ARNBERG, HENRIK		
Examiner	Art Unit		
GYAN CHANDRA	1646		

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 21 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires _____months from the mailing date of the final rejection. a) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. 🔲 The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below): (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: _____. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) 🔲 will not be entered, or b) 🛛 will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 16, 18, 21-26 and 32-36. Claim(s) withdrawn from consideration: __ AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered

- 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. \square The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

- 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
- 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s).

13. Other: .

/Robert Landsman/ Primary Examiner, Art Unit 1647 Continuation of 11 does not place the application in condition for allowance because:

Applicant's response filed on 7/21/2010 is acknowledged and fully considered.

Response to Arguments

Claim Rejections - 35 USC § 102-maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 18, 22-26, and 36 remain rejected under 35 U.S.C. 102(e) as being anticipated by Erickson-Miller et al (US pub. No. 20070105824) for the reasons of record on pg. 2-5 of the office action of 5/26/2010 and as discussed below.

Applicants argue that Erickson-Miller discusses the use of non-peptide thrombopoietin (TPO) receptor antagonists for the treatment of a very broad range of conditions, including epilepsy, periodontal asphyxia, glaucoma, AIDS, and male pattern baldness. They argue that Erickson-Miller teaches that non-peptide TPO agonist can be co-administered with other agents for treating excessive bone loss which includes periodontal disease and gingivitis but they argue that GM-CSF is not known and was not suggested as being able to treat excessive bone loss or cartilage or matrix degradation. Applicants argue that Erickson-Miller teaches using GM-CSF with TPO because GM-CSF (as other agent) has anti-apoptotic, survival or proliferative properties for stem cells, or other cells expressing TPO receptors. They argue that gingival cells are not known to express TPO receptors. Applicants argue that in claims 15 and 16 GM-CSF and TPO agonist are being used for hematopoietic cell mobilization.

Applicants' arguments have been fully considered but they are not persuasive because Erickson-Miller et al teach treating a degenerative disease including a periodontal disease such as gingivitis, which can be due to a bacterial infection (see claim 5). Because Erickson-Miller et al teach that periodontal diseases and gingivitis can be treated by co-administering TPO agonist and an agent such as GM-CSF, the prior art of record anticipates the instantly claimed invention. Applicants' arguments that that gingival cells are not known to express TPO receptors have been fully considered but they are not persuasive because the issue is not whether gingival cells express TPO receptor or how GM-CSF treats gingivitis. The issue is whether Erickson-Miller et al teach administering a composition comprising GM-CSF to treat a periodontal disease or gingivitis and they clearly do. Regarding Applicants' arguments that Erickson-Miller et al teach using GM-CSF because of its anti-apoptotic properties have been fully conidered but they are not persuasive becaue the administration of a composition comprising GM-CSF would still treat gingivitis, unless evidence to contrary. Therefore, the prior art of record anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue. 2.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21 and 32-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson-Miller et al (US pub. No. 20070105824) in view of O'Uchi et al (US Patent No. 6,682,718) for the reasons of record on pg. 5-8 of the office action of 5/26/10 and as discussed

Applicants argue that one of the ordinary skill in the art would not have motivated to combine the two references because the rerference Erickson-Miller et all teach treating bone loss using a TPO agonist and an agent (e.g., GM-CSF) which is know for anti-apoptotic activity. They argue that Erickson-Miller suggests using TPO agonist and bisphosphonates for the treatment of periodontal disease and suggests the use of non-peptide TPO receptor agonists and GM-CSF for treating hematopoietic cell mobilization, stem cells and cells expressing TPO receptros. They argue that the combination of Erickson-Miller and O'Uchi teaches away from the use of Ericson-Miller use a TPO agonist and GM-CSF for treating a conditon related to hematopoietic cell mobilation and therefore, one of the ordinary skill in the art would not necessarily administer a composition comprising GM-CSF locally.

Applicants' arguments have been fully considered but they are not persuasive because the reference Erickson-Miller et al clearly teach treating a periodontal disease or gingivitis by administering a composition comprising GM-CSF as discussed above. Therefore, the teachings of the prior art is not only limited to administering GM-CSF for treating hematopoietic cell mobilization as argued by Applicants. The reference O'Uchi et al teaches injecting a composition into periodontal tissues around alveolar bone, namely into gingiva, alveolar mucosa, sublingual mucosa, palate part and the like that (col. 4, lines 25+). Therefore, one of the ordinary skill in the art would be

Continuation Sheet (PTO-303)

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motivated to administer the composition comrpising GM-CSF as taught by Erickson-Miller et al locally as taught by O'Uchi et al to treat a periovonatal disease such as gingivitis.

Gyan Chandra AU 1646